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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,664	06/26/2003	Takatomo Hisamatsu	018961-063	3993

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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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06/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/603,664

Applicant(s)

HISAMATSU ET AL.

Examiner

Natalie Pous

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/30/05,12/30/04,6/28/04,12/10/03,11/12/03,6/26/03.

DETAILED ACTION

Response to Arguments

Regarding the combination of Wijeratne and Berg

Applicant's arguments filed 4/11/07 have been fully considered but they are not persuasive. Applicant argues that Wijeratne does not disclose or suggest a catheter comprising a distal shaft wherein at least the front portion is configured as a groove portion having a groove as recited in claim 1. As described in the previous office action, examiner concedes that Wijeratne does not teach this feature, however, the combination of Wijeratne and Berg does, and thus this argument is moot. Applicant further argues that Berg fails to cure the deficiencies of Wijeratne et al., in particular that Berg fails to teach a catheter having a distal shaft which is connected at a front portion to a balloon and wherein at least the front portion of the distal shaft is configured as a grooved portion having a groove. Examiner respectfully disagrees. Since Wijeratne does teach a catheter having a distal shaft, which is connected at a front portion to a balloon as described in the previous office action, it is not necessary for Berg to teach this feature, thus applicant's arguments with respect to this feature are moot. Examiner sustains that the advantages provided by the grooved portions of Berg in combination with the device of Wijeratne would have been obvious to one of ordinary skill in the art at the time the invention was made, and thus examiner sustains the previous rejection.

Regarding the combination of Keith and Berg

Applicant's arguments filed 4/11/07 have been fully considered but they are not persuasive. Applicant argues that Keith does not disclose or suggest a catheter

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comprising a distal shaft wherein at least the front portion is configured as a groove portion having a groove as recited in claim 1. As described in the previous office action, examiner concedes that Keith does not teach this feature, however, the combination of Keith and Berg does, and thus this argument is moot. Examiner sustains that the advantages provided by the grooved portions of Berg in combination with the device of Keith would have been obvious to one of ordinary skill in the art at the time the invention was made, and thus examiner sustains the previous rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 3, 5, 6, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al. (US 6036670) in view of Berg et al. (US 5911715).

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Wijeratne teaches a catheter comprising the following: a proximal shaft (32); a distal shaft (22) connected to a front portion of said proximal shaft; a hub (34) provided to the rear side of said proximal shaft; a balloon (21) provided at a front portion of said distal shaft; an inner tube shaft (23) coaxially extends through said distal shaft and said balloon and connected at a distal end of said balloon (fig. 1); a balloon lumen for communicating said hub to the inside of said balloon; and a guide wire lumen (23) for allowing a guide wire to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (25) positioned on the distal side from a front end of said balloon and a proximal side aperture (26) positioned on the rear side from a rear end of said balloon;

Wijeratne fails to teach the following:

- wherein at least a front portion, positioned on the rear side from said balloon, of said distal shaft is configured as a grooved portion having a groove, said grooved portion has a distal end locate near a connection portion between said balloon and said distal shaft and extends toward a proximal side of said distal shaft
- wherein said groove is formed into spiral shape or annular shape.
- wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter.
- wherein the depth of said groove is in a range of 30 to 90% of the wall thickness of said distal shaft.

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- wherein the depth of said groove is changed in the direction toward the distal end of said catheter.
- wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in said second region is larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region.
- wherein said grooved portion is provided at a portion adjacent to said balloon.
- wherein said groove is formed in an outer surface of said distal shaft.

Berg teaches a guide catheter capable of carrying a balloon wherein, at least a front portion, of said distal shaft (56) is configured as a grooved portion having a groove (61), said grooved portion has a distal end locate near a connection portion (it is noted that the term near is broad and may encompass a location anywhere along the device, and further a connection portion may simply be the transition between balloon and the distal shaft portion) between said balloon and said distal shaft and extends toward a proximal side of said distal shaft, wherein said groove is formed into spiral shape or annular shape (fig. 10), wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein the depth of said groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal

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side, and the depth of said groove in said second region is larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region (fig. 11c) and wherein said groove is formed in an outer surface of said distal shaft (fig. 9) in order to provide a device having increased flexibility for better maneuverability. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Wijeratne with the grooved portion as taught by Berg in order to provide a device having increased flexibility for better maneuverability.

Claims 1, 2, 7, 8, 10-14, 16-20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith (US 5217482) in view of Berg (US 5911715).

Keith teaches a catheter comprising the following:

- a proximal shaft (22); a distal shaft (66) connected to a front portion of said proximal shaft (22); a hub (42) provided to the rear side of said proximal shaft; a balloon (26) provided at a front portion of said distal shaft (fig. 1); an inner tube shaft (84) coaxially extends through said distal shaft and said balloon and connected at a distal end of said balloon (fig. 1) balloon lumen (106) for communicating said hub (Column 5, proximate lines 55-58) to the inside of said balloon; and a guide wire lumen (52) for allowing a guide wire (50) to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (94) positioned on the distal side from a front end of said balloon (26)

and a proximal side aperture (92) positioned on the rear side from a rear end of said balloon (26);

- a proximal shaft (22) having a high rigidity (Column 6, proximate lines 60-65), a distal shaft (66) provided on a front portion of said proximal shaft so as to be in fluid communication with said proximal shaft (Fig. 2) and having a rigidity lower than that of said proximal shaft (Column 8, proximate lines 36-40); a hub (42) connected to the vicinity of a rear end of said proximal shaft (22) and configured to allow a pressure applying apparatus to be connected to said hub (Column 5, proximate lines 55-58); a balloon (56) provided on a front side of said distal shaft so as to be in fluid communication with said distal shaft and a guide wire lumen (52) for allowing a guide wire to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (94) positioned on the front side from a front end of said balloon and a proximal side aperture positioned on the rear side (92) from a rear end of said balloon;
- wherein said distal shaft is made from a polymer material having a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cm² or more (Column 7, proximate lines 34-36). Keith teaches wherein the distal shaft is formed of a high-density polyethylene, which inherently has a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cm².
- wherein said distal shaft has a distal portion (34) and a proximal portion (110), and the rigidity of said proximal portion (110) of said distal shaft is lower than that

of said proximal shaft (22) and is higher than that of said distal portion (34) of said distal shaft (Column 9, proximate lines 1-10).

Keith fails to teach the following:

- wherein at least a front portion, positioned on the rear side from said balloon, of said distal shaft is configured as a grooved portion having a groove said grooved portion has a distal end locate near a connection portion between said balloon and said distal shaft and extends toward a proximal side of said distal shaft
- A catheter according to claim 12, wherein said groove is formed into spiral shape or annular shape.
- A catheter according to claim 12, wherein said grooved portion is provided at a portion adjacent to said balloon.
- wherein said groove is formed in an outer surface of said distal shaft.
- wherein said grooved portion is positioned on the rear side from said balloon
- wherein the pitch of said spiral or annular groove is changes over the length of the grooved portion of the distal catheter

Berg teaches a guide catheter capable of carrying a balloon wherein, at least a front portion, of said distal shaft (56) is configured as a grooved portion having a groove (61), said grooved portion has a distal end locate near a connection portion (it is noted that the term near is broad and may encompass a location anywhere along the device, and further a connection portion may simply be the transition between balloon and the distal

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shaft portion) between said balloon and said distal shaft and extends toward a proximal side of said distal shaft, wherein said groove is formed into spiral shape or annular shape (fig. 10), wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein the depth of said groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in said second region is larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region (fig. 11c) and wherein said groove is formed in an outer surface of said distal shaft (fig. 9) in order to provide a device having increased flexibility for better maneuverability. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Keith with the grooved portion as taught by Berg in order to provide a device having increased flexibility for better maneuverability.

Regarding the limitation wherein the pitch of said spiral or annular groove is changes over the length of the grooved portion of the distal catheter, Berg teaches a catheter wherein the grooved portion may have varying width and depths in order to provide variation in flexibility from groove to groove. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Keith with varying pitch of the spiral grove in order to provide variation in flexibility along the grooved portion.

Claims 4, 9, 15, 21, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Keith and Berg as applied to claims 1 and 12 above, and further as a matter of design choice.

The combination of Keith and Berg teaches all of the limitations of preceding dependent claims 1 and 12 as previously disclosed, but fails to describe the following:

- wherein the depth of said groove is in a range of 30 to 90% of the wall thickness of said distal shaft.
- wherein the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more.

Regarding the limitations wherein the groove is in a range of 30 to 90% of the wall thickness of said distal shaft and the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more, the combination of Keith and Berg teaches a device wherein the grooves are in place in order to provide a smooth transition from the proximal rigid portion to the more flexible distal portion (Berg), but does not teach the exact depth of the grooves in relation the thickness of the shaft. It appears that the combination of Keith and Berg performs the task of providing a smooth transition from the proximal rigid portion to the more flexible distal portion equally well as that disclosed in the application. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose make the depth of the groove in a range of 30 to 90% of the wall thickness of the distal shaft and the product of an outer

diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-

6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tan-Uyen (Jackie) Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
6/11/07


(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
6/20/07